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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/590,583	06/08/2000	Tony N. Frudakis	210121.419C9	1221

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EXAMINER
SPIEGLER, ALEXANDER H

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 10/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/590,583	Applicant(s) FRUDAKIS ET AL.	
	Examiner Alexander H. Spiegler	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6, 8-57 and 60* is/are pending in the application.

4a) Of the above claim(s) *1-3,8-15 and 17-57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-6,16 and 60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5, 8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I (claims 4-7, 16 and 58-60) in Paper No. 12 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 7, 58 and 59 have been canceled, thus 1-6, 8-57 and 60 are pending. Claims 4-6, 16 and 60 have been examined on the merits, and claims 1-3, 8-15, and 17-57 have been withdrawn from consideration, as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 4-5 and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 4 and 60 are indefinite over "at least 15 amino acid residues of a breast tumor protein" because it is not clear as to what 15 amino acids can be considered as "residues of a breast tumor protein". First, it is noted that the claims are drawn to 15 amino acid residues, that is, **any** 15 amino acids encoded by SEQ ID NO: 307, not specifically even contiguous amino acids. Therefore, it is not clear as to how any random 15 amino acids could be considered as amino acid residues "of a breast tumor protein".

B) Claims 4-5 and 60 are indefinite over "the tumor protein" because this recitation lacks antecedent basis. The claim could be amended to recite, "the breast tumor protein".

C) Claim 60 is indefinite over "a diagnostic reagent" for use in a polymerase chain reaction or hybridization assay because it is not clear as to what is considered to be "a diagnostic reagent" for use in a polymerase chain reaction or hybridization assay.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 4 and 60 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 4 and 60 are directed to an isolated polynucleotide encoding at least 15 amino acids residue of a breast tumor protein. These claims can be interpreted as a polynucleotide that encodes **any** 15 amino acids encoded by SEQ ID NO: 307, not specifically even contiguous amino acids. Therefore, this claim reads on any random 15 amino acids that are encoded by SEQ ID NO: 307.

Any polynucleotide that encodes **any** 15 amino acids encoded by SEQ ID NO: 307 are inclusive of sequences from other species, mutated sequences, and allelic variants having different functional activities. This includes a large genus of nucleic acids and proteins, having unique functional activities. None of these sequences meet the written description provision of

35 USC 112, first paragraph, and therefore, the specification provides insufficient written description to support the genus encompassed by the claims.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

The skilled artisan cannot envision the detailed chemical structure of the encompassed proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Accordingly, the specification does not provide adequate written description for "an isolated polynucleotide [of SEQ IF NO: 307] encoding at least 15 amino acids residue of a breast tumor protein".

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 4-6, 16 and 60 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

Applicants are directed to MPEP § 2107, which states that when determining the utility of an application, the Examiner must, "**review the claims and the supporting written description to determine if the applicant has asserted for the claimed invention any specific and substantial utility that is credible**".

In the instant case, Applicants do not assert a specific and substantial utility that is credible or a well-established utility for SEQ ID NO: 307 or fragments thereof.

The specification contains over 200 nucleic acid sequences (pg. 9, ln. 13-15), which Applicants claim have the following, alleged utilities:

- "the polynucleotide sequences provided herein can be advantageously used as probes or primers for nucleic acid hybridization" (pg. 14, ln. 24-26)...Polynucleotide primers and probes may be used to detect the level of mRNA encoding a tumor protein, which is also indicative of the presence or absence of a cancer. In general, a breast tumor sequence should be present at a level that is at least three fold higher in tumor tissue than normal tissue" (pg. 91, ln. 9-12);

- "the present invention concerns formulation of one or more of the polynucleotide compositions for administration to a cell or an animal, either alone, or in combination with one or more other modalities of therapy " (pg. 71, ln. 4-7);

These alleged utilities summarized above are neither substantial nor specific, since they are generic in nature and applicable to a myriad of such compounds (e.g. nucleic acids). Probes and primers can be designed from **any** polynucleotide sequence, as well as, the fact that polynucleotides can be formulated to be compositions for administration to a cell or an animal, either alone, or in combination with one or more other modalities of therapy. While these

utilities are credible, they are not specific or substantial, since the specification does not disclose nucleic acid target. Since these asserted utilities are not present in mature form (i.e. no specific target), they could not be readily used in a "real world" sense", and thus, not substantial.

The specification teaches that a full-length cDNA (SEQ ID NO: 307) and its corresponding amino acid sequence (SEQ ID NO: 308) were obtained (pg. 103, ln. 23-24). However, the specification does not teach any significant or functional characteristics of the polynucleotide or its corresponding amino acid. Furthermore, the specification does not teach a well-established utility for the claimed polynucleotide.

MPEP § 2107 additionally states:

"The 35 U.S.C. 101 and 112 rejections shift the burden of coming forward with evidence to the applicant to:
(i) Explicitly identify a specific and substantial utility for the claimed invention; and
(ii) Provide evidence that one of ordinary skill in the art would have recognized that the identified specific and substantial utility was well-established **at the time of filing**".

In the instant case, Applicants have not "explicitly identif[ied] a specific and substantial utility for the claimed invention". Furthermore, the specification has not provided any evidence that "one of ordinary skill in the art would have recognized that the identified specific and substantial utility was well-established **at the time of filing**".

If Applicants traverse this rejection, Applicants should explicitly identify a specific, substantial, and credible utility for the claimed invention and establish a probative relation between any evidence of record and the originally disclosed properties of the claimed invention.

8. Claims 4-6, 16 and 60 are also rejected under 35 U.S.C. §112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial, and credible

utility or a well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 4 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Bedin et al. (Geneseq Accession No. AAT96475, February 28th, 1998)).

Bedin teaches "an isolated polynucleotide encoding at least 15 amino acid residues of a breast tumor protein, wherein the tumor protein comprises an amino acid sequence that is encoded by a polynucleotide comprising SEQ ID NO: 307" (See sequence search result #11 - Geneseq Accession No. AAT96475).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bedin et al. (Geneseq Accession No. AAT96475, February 28th, 1998), as applied to clam 4 above, and in further in view of Stratagene Catalog (1998).

Bedin teaches "an isolated polynucleotide encoding at least 15 amino acid residues of a

breast tumor protein, wherein the tumor protein comprises an amino acid sequence that is encoded by a polynucleotide comprising SEQ ID NO: 307" (See sequence search result #11 - Geneseq Accession No. AAT96475). Specifically, Bedin teaches that Geneseq Accession No. AAT96475 represents a nucleic acid sequence that can be used in the diagnosis of multiple sclerosis and rheumatoid arthritis (See sequence search result #11). Bedin does not teach this nucleic acid in a kit.

However, reagent kits for performing DNA assays were conventional in the field of molecular biology at the time the invention was made. In particular, the Stratagene catalog discloses that kits provide the advantage of pre-assembling the specific reagents required to perform an assay and ensure the quality and compatibility of the reagents to be used in the assay. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the nucleic acid of Bedin and a "diagnostic reagent" for use in PCR or hybridization assays in a kit for the expected benefits of convenience and cost-effectiveness for practitioners of the art.

Conclusion

13. No claims are allowable.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014. Applicant is also invited to contact the TC 1600 Customer Service Hotline at (703) 308-0198.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Alexander H. Spiegler
October 10, 2002

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
10/10/02